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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,124	02/07/2002	John M. Pezzuto	7500-0004.10	2746

23980 7590 11/23/2004

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EXAMINER	
JONES, DWAYNE C	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,124	PEZZUTO ET AL.	
	Examiner	Art Unit	
	Dwayne C Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *the amendment of 29JUL2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68,70-72,74-77,84-87 and 94-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *68,70-72,74-77,84-87 and 94-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/005,114.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 68, 70-72, 74-77, 84-87, and 94-99 are pending.

2. Claims 68, 70-72, 74-77, 84-87, and 94-99 are rejected.

3. Claims 69, 73, 92, and 93 are canceled as per the amendment of July 29, 2004.

Response to Arguments

4. Applicants' arguments filed July 29, 2004 have been fully considered but they are not persuasive. Applicants make the following arguments. First, applicants submit Carson et al. and Ashida do not teach nor suggest that resveratrol may be modified for oral or parenteral administration. Second, applicants purport that Carson et al. and Ashida do not teach or suggest the microemulsion limitation.

5. First, applicants submit Carson et al. and Ashida do not teach nor suggest that resveratrol may be modified for oral or parenteral administration. Because the instantly filed claims are composition claims of resveratrol and emollients and the fact that the prior art references of Carson et al. and Ashida also teaches of a composition of resveratrol and emollients, the instantly claimed invention is rendered obvious. Also the term resveratrol embraces its geometric isomers, in particular *cis*- and *trans*-resveratrol. In addition, instant claim 68 has two intended use clauses, one "for use in treating skin conditions ..." and the other is "for oral or parenteral administration." Both of these recitations do not result in a structural difference between the claimed subject matter and Carson et al. If the prior art structure is capable of performing the intended use,

then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

6. Second, applicants purport that Carson et al. and Ashida do not teach or suggest the microemulsion limitation. It is again pointed out that Carson et al. also teach of using various types of emollients such as polyethylene glycol as well as various other types of emollients, (see from column 5, line 49 to column 6, line 37). Carson et al. also teach of the presence of polyols, (see column 4, lines 28-33), silicone compounds (see column 5, lines 49-54), water (see column 4, lines 26, and 44-49), and propylene glycol, (column 6, line 5). Carson et al. also teach that these compounds may be formulated in lotions, creams or even a gel, (see column 6, lines 50-63). Carson et al. also teach that these compounds may be formulated in lotions, creams or even a gel, (see column 6, lines 50-63). The determination of a dosage as well as modes and methods of administration having the optimum therapeutic index is well within the purview of the skilled artisan in the art, and the artisan would be motivated to determine optimum amounts and modes of administration. Moreover, Carson et al. do teach of a composition of resveratrol along with emollients, (see columns 4 and 5) and it is known in the art that emulsions are simply a suspension of one liquid in a second liquid, the skilled artisan would be able to determine and prepare well-known pharmaceutical formulations in various modes of administration, such as a microemulsion. In addition, Ashida teach of resveratrol along with pharmaceutically acceptable excipients and emollients. The claimed subject matter is limited to a composition containing resveratrol, which is what the prior art references of Carson et al. and Ashida also

teach. One having ordinary skill in the art would have been motivated to prepare known compositions, such as resveratrol, in well-known and well-established pharmaceutical preparations, which would obviously include microemulsions. Accordingly, these arguments by applicants are not found persuasive and convincing.

Claim Rejections - 35 USC § 112

7. The rejection of claims 68-77, 84-87, 92, and 94-99 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating skin conditions, diseases, disorders associated with inflammation of psoriasis, contact dermatitis, atopic dermatitis, actinic keratosis, keratinization disorders, epidermolysis bullosa diseases, exfoliative dermatitis, seborrheic dermatitis, erythemas, discoid lupus erythematosus, dermatomyositis, does not reasonably provide enablement for treating other types of skin conditions, diseases, disorders associated with inflammation, including skin cancer as well as inhibiting cellular events associated with tumor initiation, promotion, and progression is with drawn in response to the amendment of July 29, 2004.

8. The rejection of claims 68-77, 84-87, 92, and 94-99 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is with drawn in response to the amendment of July 29, 2004.

Claim Rejections - 35 USC § 102

9. Claims 68, 84-87, 92-95, 98, and 99 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Carson et al. of U.S. Patent No. 6,270,780, possessing an

effective filing date of July 25, 19971997 is removed in is removed in response to the amendment of July 29, 2004.

10. The rejection of claims 68 and 92 under 35 U.S.C. 102(b) as being clearly anticipated by Hou, R. of CN 127070 A of July 24, 1996 is removed in response to the amendment of July 29, 2004.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. The rejection of claims 68, 70-72, 74-77, 84-87, and 94-99 under 35 U.S.C. 103(a) as being unpatentable over Carson et al. of U.S. Patent No. 6,270,780, possessing an effective filing date of July 25, 19971997 is maintained and repeated for both the above-stated and reasons of record. Carson et al. teach of topical compositions of resveratrol in amounts ranging from about 0.0002 to about 10 % by weight of the composition, (see column 4, lines 13-15).

15. Carson et al. also teach of using various types of emollients such as polyethylene glycol as well as various other types of emollients, (see from column 5, line 49 to column 6, line 37). Carson et al. also teach of the presence of polyols, (see column 4, lines 28-33), silicone compounds (see column 5, lines 49-54), water (see column 4, lines 26, and 44-49), and propylene glycol, (column 6, line 5). Carson et al. also teach that these compounds may be formulated in lotions, creams or even a gel, (see column 6, lines 50-63). Carson et al. also teach that these compounds may be formulated in lotions, creams or even a gel, (see column 6, lines 50-63). In addition

16. The instant composition differs in the specific range of dosages claimed. The determination of a dosage having the optimum therapeutic index is well within the purview of the skilled artisan in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug. Accordingly, Carson et al. provides the skilled artisan with the motivation to vary the amounts as well as the excipients in the topical formulation disclosed by Carson et al. Moreover, a recitation of

the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

17. The rejection of claims 68, 70-72, 74-77, 84-87, and 94-99 under 35 U.S.C. 103(a) as being unpatentable over Ashida of JP 4093288410 A, which has a publication date of December 22, 1997 is maintained and repeated for both the above-stated and reasons of record. Ashida discloses of a cosmetic formulation, which contains resveratrol in amounts ranging from about 0.001 to 5 wt. %, (see abstract). Although Ashida may be silent to the derivatives of resveratrol as well as the specific pharmaceutically acceptable excipients and emollients, it is well within the level of the skilled artisan to determine optimum amounts of the active ingredient and also with the types and amounts of the pharmaceutically acceptable excipients, diluents, emollients, etc., The determination of a dosage having the optimum therapeutic index is well within the purview of the skilled artisan in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug. Accordingly, the skilled artisan is provided with the motivation to vary the amounts as well as the excipients in the topical formulation disclosed by Ashida. Moreover, a recitation of the intended use of the claimed invention must result in a structural difference between the

claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

18. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-

0578. The examiner can normally be reached on Mondays, Tuesdays, Thursday, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (703) 872-9306.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see http://pair-direct.uspto.gov. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

DWAYNE JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
November 19, 2004